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Short-term (30-day) Outcome of Endovascular Treatment of Abdominal Aortic Aneurysm: Results from the Prospective Registry of Endovascular Treatment of Abdominal Aortic Aneurysms (RETA)

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Objectives: *to assess the early morbidity and mortality of a new treatment, the endovascular repair of abdominal aortic aneurysms, during its introduction into clinical practice.*
Design: *a prospective voluntary registry collecting demographic and risk factor data, details of aneurysm morphology, procedure performed, immediate and 30-day outcomes.*
Setting: *thirty-one U.K. centres performing endovascular repair submitted data.*
Results: *six hundred and eleven cases were registered in 3 years of data collection (January 1996 to December 1998). Four per cent of patients received an aortic tube device, 60% an aorto-bi-iliac device and 36% an aorto-uni-iliac device and a crossover graft (AUIC). Conversion to open repair was required in 5% of cases, with more conversions in the AUIC group (OR 2.9 (95% CI: 1.3–6.4)* $p = 0.01$*) Post procedure complications occurred in 25% of cases. Unfit patients had significantly more complications than fit patients (35% vs 20% for fit patients (OR 1.8 (95% CI: 1.2–2.7)* $p = 0.007$*)). At 30 days aneurysms were excluded in 90% of cases. Endoleaks were more common in larger aneurysms (2% if aneurysms were <6 cm in diameter vs 10% if >6 cm, OR 5.6 (95% CI: 2.1–14.9)* $p = 0.0006$*). The overall mortality was 7% but was significantly higher for AUIC devices, (4% for combined aortic tube and bi-iliac devices (AT/BI) vs 12%, OR 2.6 (95% CI: 1.2–5.9* $p = 0.018$*), and unfit patients (4% for fit patients vs 18%, OR 4.3 (95% CI: 2.0–9.5)* $p < 0.001$*).*
Conclusions: *endovascular repair is feasible with short-term outcomes comparable to those of conventional surgical repair. In unfit patients the possible benefit in life expectancy gain must to be balanced against the morbidity and mortality of the procedure.*

Introduction

Since it was first described in 1991, the feasibility of endovascular treatment of abdominal aortic aneurysm (AAA) has been firmly established.[1–5] In essence, during endovascular repair the endograft is positioned within the aorta by a transfemoral or transiliac route to exclude the aneurysm sac from the circulation; the graft being anchored by one or more metallic stents below the renal arteries. The technique, though currently requiring an arterial cutdown, avoids the need for surgical exposure of the aorta and aortic cross clamping and as such is "minimally invasive", with potentially reduced morbidity and mortality. This potential has resulted in it being offered to patients with severe co-morbid conditions who would therefore be considered unfit for conventional surgical repair, as well as to fit patients. This raises important ethical and consent issues in unfit patients if conversion to an open repair becomes necessary because of complications. Not all patients can be treated endovascularly, with aneurysm morphology being the major determinant of suitability. At present the proportion of aneurysms suitable for endovascular repair are estimated to be between 30–50%, with aorto-uni-iliac devices advocated as being usable in a larger proportion of cases.[6]

Though there has been considerable enthusiasm for endovascular repair of AAA, there have been concerns that the technique may be widely introduced prior to proper evaluation.[7] The Registry of Endovascular Treatment of Abdominal Aortic Aneurysms (RETA) was established as a voluntary database overseen by the Joint Working Party of the Vascular Surgical Society

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of Great Britain and Ireland and the British Society of Interventional Radiology.[8] Its purpose is to assess the safety and efficacy of this new and rapidly changing technology during its introduction into clinical practice. We present the short-term (30-day) morbidity and mortality data from the first 3 years (1 January 1996 to 31 December 1998) of data collection.

Methods

Registry details

The registry was co-ordinated at the Sheffield Vascular Institute on behalf of the Joint Working Party of the Vascular Surgical Society (VSS) of Great Britain and Ireland and the British Society of Interventional Radiology (BSIR). Data submission was voluntary with all United Kingdom members of the VSS and BSIR asked to submit their cases on a simple registration form.

The case registration form recorded details of patient age, clinical indication for the procedure, co-morbidity precluding conventional repair, anaesthetic risk, aneurysm morphology, device used, procedure details (anaesthesia used, length of procedure and blood loss), plus immediate and 30-day outcomes and length of hospital stay. Immediate outcomes recorded were: aneurysm exclusion at the end of the procedure; whether additional endovascular procedures, additional surgical treatments or conversion to an open repair were required, and whether there was evidence of endoleak (continued filling of the aneurysm sac) at the end of the procedure. Complications post procedure and their treatment were recorded. At 30 days the main outcomes recorded were exclusion of the aneurysm sac, mortality, major amputation, and presence of endoleak.

Analysis

For the purposes of analysis subgroups of patients were identified. There were two main types of device: (i) the aorto-uni-iliac (AUI) devices, which require a more surgical technique with a crossover graft, but can be used on a larger proportion of aneurysms;[6] and (ii) the aortic tube or bi-iliac (AT/BI) devices which involve a more endovascular technique. The AUI device group contains a large number of "home made" devices constructed by using available materials, such as Palmaz stents and Polytetrafluoroethylene (PTFE) graft material, the device is constructed for each case, whereas the AT/BI devices are commercially available ready-made. The results for these two subgroups (AUI and crossover group (AUIC), and AT/BI group) have been analysed separately. Because of concerns about the treatment of "unfit" patients, subgroups of "fit" and "unfit" were analysed separately. Patients corresponding to American Society of Anaesthesiology (ASA) grade IV or V or who were specified as unsuitable for conventional repair because of co-morbidity were deemed "unfit"; ASA grade I–III were deemed "fit". Another subgroup of patients were identified as "fit" by ASA grade but "unsuitable" for conventional open repair because the presence of, for example, a hostile abdomen or an inflammatory aneurysm made the open procedure high risk. As larger aneurysms may be more difficult to treat, subgroups of AAA diameter <6 cm and >6 cm were analysed separately. This paper focuses on complications and 30-day outcomes which are presented for the total data set as descriptive statistics. Chi-squared tests of independence (for categorical data) and *t*-tests (for continuous data) were used to assess differences in baseline data. Logistic regression was used to compare differences in outcomes between groups with adjustments made for available confounders (fitness for repair, indication for repair, age, device type, aneurysm diameter) as appropriate. Cox proportional hazard models were used to assess differences in length of in-patient stay, adjusted for confounders of patient age, indication for repair, fitness and device type.

Results

Between 1 January 1996 and 31 December 1998, 611 cases were submitted to the registry from 31 centres. A median of 11 cases (range 1–115) were submitted per centre. The number of cases submitted increased from 146 in 1996, to 183 in 1997 and 282 in 1998.

Basic patient characteristics are shown in Table 1. The mean (range; S.D.) age of patients was 72 (44–93; 7.56) years. There was no statistically significant difference in age between patients treated with an AT/BI device and an AUIC device (71 years vs 72 years, respectively; (mean difference $+1.1$ years, 95% CI: $+2.4$; -0.2, $p=0.08$)), nor between fit patients and unfit patients (71 years vs 71 years, respectively; (mean difference -0.2 years, 95% CI: $+1.3$; -1.6, $p=0.8$)). Patients with smaller aneurysms were significantly younger than those with aneurysms >6 cm in diameter (70 years vs 72 years, respectively; (mean difference $+1.9$ years (95% CI: $+3.2$; -0.4) $p=0.002$)).

Table 1. Patient characteristics.

Characteristics	All	AT/BI	AUIC	OR (95% CI)	*p* value
Age	72	71	72	Mean 1.1 year (+2.4; −0.2)	0.08
Unfit patients	131/603 (22%)	57/387 (15%)	74/216 (34%)	3.0 (2.0–4.5)	<0.001
Fit, unsuitable for open repair	36/472 (8%)	16/330 (5%)	20/142 (14%)	3.2 (1.6–6.4)	0.001
Aneurysm size >6 cm	304/585 (52%)	170/380 (45%)	134/205 (65%)	2.3 (1.6–3.3)	<0.001

AT/B: Aortic tube and bi-iliac devices; AUI: aorto-uni-iliac devices.

Endovascular repairs were performed electively for asymptomatic aneurysms in 82% (502/608) of cases, electively for symptoms in 14% (86/608), acutely for non-ruptured AAA in 2% (10/608) and for acute ruptured AAA in 2% (10/608) (missing data $n=3$).

Overall 22% (131/603; missing data $n=8$) of cases were considered "unfit". In the AT/BI group 15% (57/387) were unfit compared to 34% (74/216) for the AUIC group. Throughout the results are presented so as to represent the odds of an outcome in the second stated group, so the odds of being "unfit" when comparing the AT/BI group and the AUIC group are 3.0 (OR 3.0 (95% CI: 2.0–4.5) $p<0.001$).

Of the 472 fit patients, 36 (8%) were considered "fit" but "unsuitable" for conventional open repair.

Sixteen/330 (5%) of the fit patients in the AT/BI group were considered unsuitable for conventional repair compared to 20/142 (14%) of the AUIC group (OR 3.2 (95% CI: 1.6–6.4) $p=0.001$).

The mean aneurysm diameter was 6.1 cm (range: 3.6–14; SD: 1.17). A smaller proportion of patients treated with an AT/BI device had larger aneurysms (>6 cm in diameter): 45% (170/380) vs 65% (134/205) of those treated with an AUIC device (OR 2.3 (95% CI: 1.6–3.3) $p<0.001$). Patients with larger aneurysms were more unfit: 14% (38/276) were unfit if the aneurysm was <6 cm in diameter against 27% (81/301) unfit if the aneurysm was >6 cm in diameter (OR 2.3 (95% CI: 1.5–3.5) $p<0.001$).

Four per cent (26/611) of patients received an aortic tube device, 60% (366/611) an aorto-bi-iliac device and 36% (219/611) an aorto-uni-iliac device and a crossover graft. The type of devices used are shown in Table 2.

General anaesthesia was used alone in 92% (560/603) of cases. Three per cent (19/603) of cases had both general and regional anaesthesia. Regional anaesthesia was used alone in 5% (31/611) of cases. Fit patients had general anaesthesia alone in 95% (446/472) of cases against 82% (107/131) of unfit patients (OR 0.9 (95% CI: 0.8–0.9) $p<0.001$). In unfit patients regional anaesthesia was used more commonly than in the fit; regional anaesthesia was used alone in 11% (14/131) of unfit patients and 4% (17/472) of fit patients (OR 0.3 (95% CI: 0.1–0.6) $p<0.001$).

Table 2. Endoprosthesis type.

Device	Number (%)
Ancure (Guidant EVT Europe)	36 (6)
AneurX (Medtronic)	128 (21)
Bard device (Bard, UK)	5 (1)
Excluder (Gore)	1 (<1)
Gianturco-Dacron ("Home made")	107 (17)
Gianturco-PTFE ("Home made")	14 (2)
Ivanchev-Malmo ("Home made")	2 (<1)
Palmaz/PTFE ("Home made")	65 (11)
Talent (Medtronic)	60 (10)
Vanguard (Boston Scientific)	162 (27)
Zenith (Perth) (Cook, U.K.)	26 (4)
Missing	5 (<1)
Total	611 (100)

The median length of procedure was 2 h 30 min (range: 1–9 h) and the median blood loss 400 ml (range: 50–7000).

Immediate post procedure outcomes for all patients and by device type are shown in Table 3. Conversion to open repair (OR) was required in 5% (32/611) of cases overall. The reasons for conversion to OR are shown in Table 4. The rate of conversion improved in the last year of submission to the registry (Fig. 1), being 9% (13/146) in 1996, 8% (14/183) in 1997 and 2% (5/282) in 1998 ($p=0.002$).

In-hospital complication (up to 30 days post procedure) rates are shown in Table 5 for all patients and by device type. Details of these in-hospital complications are given in Table 6.

Thirty-day outcome data was available for 96% (588/611) of cases. Details of 30-day outcomes for all cases, by device type, fitness and AAA size are shown in Tables 7 and 8. Causes of death at 30 days post procedure are detailed in Table 9. Conversion to OR for fit patients carried a mortality of 20% (5/25) and if an unfit patient required conversion mortality rose to 66% (4/6).

Length of post-procedure hospital stay was established from the date of procedure to discharge, the

Table 3. Immediate outcomes.

Characteristics	All	AT/BI	AUIC	OR (95% CI)	*p* value
Aneurysm excluded	465/611 (76%)	293/392 (75%)	172/219 (79%)	1.5 (0.9–2.4)	0.06
Additional endovascular procedures	71/611 (11%)	59/392 (15%)	12/219 (6%)	0.3 (0.1–0.6)	<0.001
Additional surgical procedures	30/611 (5%)	21/392 (5%)	9/219 (4%)	0.6 (0.2–1.5)	0.2
Conversion to open repair	32/611 (5%)	13/392 (3%)	19/219 (9%)	2.9 (1.3–6.4)	0.01

AT/BI: Aortic tube and bi-iliac devices; AUI: aorto-uni-iliac devices.
Aneurysm exclusion: no flow into aneurysm sac angiographically at end of procedure.

Table 4. Reasons for conversion to open repair (immediate conversions $n=30$, elective conversion $n=2$).

Reason for conversion to open repair	Number
Migration of device	9
Unable to advance or position prosthesis	7
Rupture during deployment	3
Persistent endoleak	3
Renal artery dissection/occlusion	2
Acute ruptured AAA; continued haemorrhage	2
Hypotensive collapse, converted. No leak ? vasovagal	1
Graft slipped off deployment balloon	1
Limb incorrect size	1
Device too small, retrieved, elective conversion	1
Failure of deployment, explanted electively	1
No reason stated	1
Total	32 (5%)

AAA: Abdominal aortic aneurysm.

median (range) length of stay was 6 (2–>30) days. Patients treated with an AT/BI device had a shorter post-procedure length of stay, median (range) of 5 (2–>30) days compared to 8 (2–>30) days for those treated with an AUIC device ($p=0.001$). Unfit patients had a longer post-procedure length of stay with a median (range) of 6 (2–30) days vs 5 (2–30) days for fit patients ($p=0.42$).

Discussion

Methodological issues

The RETA registry was established as a means of monitoring the early introduction of endovascular repair of AAAs during its phase of introduction, prior to the establishment of a randomised controlled trial (RCT). Although endovascular treatment is in its infancy, with rapid technological development it was

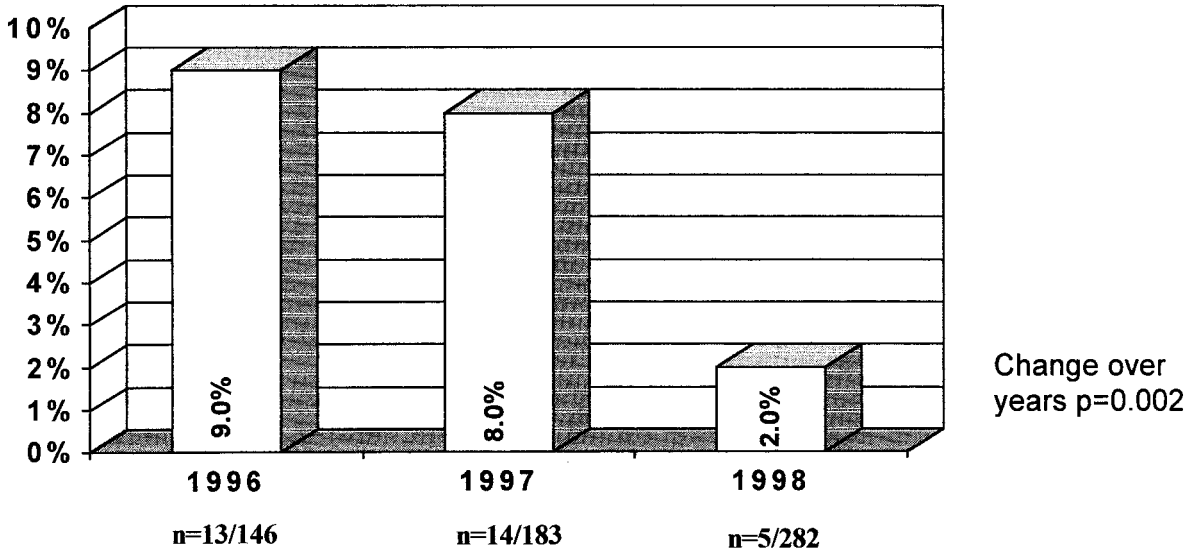

Fig. 1. Conversion rate by year.

Table 5. In-hospital complications.

Characteristics	All	AT/BI	AUIC	OR (95% CI)	*p* value
All complications	155/611 (25%)	78/392 (20%)	77/219 (35%)	1.8 (1.2–2.7)	0.007
Technical complications	34/611 (6%)	14/392 (4%)	20/219 (9%)	2.6 (1.2–5.6)	0.015
Wound complications	46/611 (8%)	27/392 (7%)	19/219 (9%)	1.1 (0.5–2.3)	0.8
Renal failure	27/611 (4%)	14/392 (4%)	13.219 (6%)	2.1 (0.9–5.2)	0.1
Other medical complications	78/611 (13%)	33/392 (8%)	45/219 (20%)	2.1 (1.2–3.5)	0.008

AT/BI: Aortic tube and bi-iliac devices; AUI: aorto-uni-iliac devices.

Table 6. Complications up to 30 days post procedure.

Complication	Number
Technical complication $n=34$ (6%)	
Endoleak	10
Embolisation (Macro or micro)	9
Graft or limb occlusion	6
Stent stenosis/kink	4
Enteric fistula-tunnel for crossover	1
Limb too short	1
Renal infarction on CT	1
Both CIAs covered, buttock claudication	1
Not stated	2
Wound complication $n=46$ (8%)	
Haematoma/haemorrhage/pseudoaneurysm	22
Infection	16
Access artery thrombosis	4
Seroma or lymph leak	3
Femoral nerve weakness	1
Renal failure $n=27$ (4%)	
Other medical complication $n=78$ (13%)	
Cardiovascular: MI/arrhythmia/LVF	23
Respiratory: PE/infection	14
Cerebrovascular accident/confusion	9
Fever/PUO: no cause found	9
Ileus	5
Urinary problems	5
MSOF	3
DVT	2
Other	8

CT: Computed tomography; CIA: common iliac artery; MI: myocardial infarction; LVF: left ventricular failure; PE: pulmonary embolism; PUO: pyrexia of unknown origin; MSOF: multisystem organ failure; DVT: deep vein thrombosis.

felt important that this treatment should be properly evaluated so that inappropriate claims are not made for the new "minimally invasive" treatment.[9] As a first step the use of a registry can be of value in assessing new treatments, but it is important to understand the limitations of their use.[10–12] The only way to eliminate confounding and obtain clear results when comparing interventions is to use randomisation. Registries have a number of problems that are common to all observational datasets, and specific problems of their own. As data submission is voluntary there is a risk of bias in the data submitted to the registry. Since there was no attempt with the RETA registry to validate the number of cases submitted by each centre, it is not possible to ascertain the amount and characteristics of data not submitted. In making comparisons between groups of patients known confounders can be allowed for in analysis. There was only limited data collected on perceived risk factors, but adjustments were necessary because of the differences in these factors between patient groups. However, in comparing groups of patients caution is necessary because of unknown confounding factors, which may be significant. The results presented represent the best estimates within the limitations of the data collected. If these problems are borne in mind then registry data can provide insight into the results of new treatments, and can be useful in planning trials, identifying future data to be collected and generating hypotheses to be tested.

Findings

All cases

The registry results confirm the feasibility of endovascular repair and give an insight into likely complication and 30-day outcome rates. Conversion to open repair occurred in 5% of cases, and when needed the mortality was high (29%). Though "minimally invasive", a 25% all complication rate in the immediate post procedure period is not insignificant. Two problems that may have been expected appear very uncommon: colonic ischaemia and distal embolisation

Table 7. Thirty-day outcomes.

Characteristics	All	AT/BI	AUIC	OR (95% CI)	*p* Value
Aneurysm excluded	526/588 (90%)	346/376 (92%)	180/212 (85%)	0.9 (0.4–1.4)	0.47
Persistent endoleaks	34/588 (6%)	22/376 (6%)	13/212 (6%)	0.6 (0.3–1.3)	0.21
Mortality – all cases	39/588 (7%)	13/376 (4%)	26/212 (12%)	2.6 (1.2–5.9)	0.018
Mortality – fit patients	16/455 (4%)	4/314 (1%)	12/137 (9%)	8.3 (2.2–31)	0.002
Mortality – unfit patients	23/126 (18%)	9/54 (16%)	14/72 (19%)	0.9 (0.3–2.5)	0.79

AT/B: Aortic tube and bi-iliac devices; AUI: aorto-uni-iliac devices.
Aneurysm exclusion: no evidence of endoleak on CT scan at 30 days.

Table 8. Thirty-day outcome by AAA size.

Characteristics	All	AAA <6 cm	AAA >6 cm	OR (95% CI)	*p* Value
Aneurysm excluded	526/588 (90%)	260/269 (97%)	244/294 (83%)	0.2 (0.09–0.4)	<0.001
Persistent endoleaks	34/588 (6%)	6/269 (2%)	29/294 (10%)	5.6 (2.1–14.9)	0.0006
Mortality	39/588 (7%)	4/269 (2%)	31/294 (11%)	4.4 (1.4–13)	0.009

AAA: Abdominal aortic aneurysm.

Table 9. Causes of death at 30 days post procedure.

Cause of death	Number
Cardiovascular: MI, LVF	18
MSOF	7
Cerebrovascular: CVA, SAH	5
Haemorrhage during procedure: AAA or IA rupture	3
Sepsis	2
Metastatic lung tumour	1
Pulmonary embolism	1
Small bowel perforation	1
Not stated	1
Total	39 (6.6%)

MSOF: Multisystem organ failure; CVA: cerebrovascular accident; SAH: subarachnoid haemorrhage; MI: myocardial infarction; LVF: left ventricular failure; AAA: abdominal aortic aneurysm; IA: iliac artery.

occurred infrequently, though distal limb embolisation did lead to amputation in one case. The majority of aneurysms were successfully excluded, though it seems that this is more difficult to achieve with larger aneurysms. This may be related to a tendency to use current device sizes in AAA necks and iliac arteries that were too large. The data to support this theory is not available in the registry. The overall mortality was reasonably low at 7%, which is comparable to other reported series,[3–5,13] but higher than the overall mortality recently reported by the EUROSTAR collaborators on a European registry.[14] However, the EUROSTAR registry data does not contain the results of using AUIC devices, and the mortality rates from the RETA registry on AT/BI devices are very similar to those reported by EUROSTAR (4% vs 3.2%). This similarity in results for AT/BI cases is probably to be expected, as at least some cases submitted to RETA were probably also submitted to the EUROSTAR registry. The RETA data is more heterogenous, reflecting a wider group of patients treated and devices used throughout the United Kingdom. Even so, these results are probably comparable to conventional surgery, particularly if only fit patients are considered.[4,15,16]

Unfit patients

Because endovascular treatment is considered minimally invasive, its use in unfit patients in whom a conventional operation is deemed high risk is appealing. However, offering this treatment, which is still unproven long-term and which we have shown has a high complication and mortality in this group, raises important ethical and consent implications. Clinicians and patients need to consider the trade-off of expected life expectancy gain from treating an aneurysm against the morbidity and mortality of the procedure itself. The potential long-term benefit in a group of patients whose principal cause of death may not be aneurysm rupture remains to be investigated. Also, conversion to OR is occasionally required for these unfit patients, because of complications during

the procedure, and in an unfit patient the mortality rate then became very high (66%).

Fit patients unsuitable for open repair

Patients with AAA in whom an open repair is relatively contraindicated because of problems such as a hostile abdomen, inflammatory aneurysm, horseshoe kidney or gross obesity, but who are otherwise fit, are a particular group that are well suited to endovascular repair. They have a good life expectancy if the AAA is successfully treated long-term. The registry shows that the 30-day mortality rate at 7% for endovascular repair is comparable to conventional surgery in fit patients suitable for open repair. However, important questions are raised in this group of patients about future endovascular device problems, as later surgical correction will remain contraindicated in the majority of patients.

Device types

The AUIC devices can be used to treat a larger proportion of aneurysms and we have shown that those treated with it tend to be older, more unfit and to have larger aneurysms. Comparisons with the AT/BI group are difficult because of these differences, which confound direct comparison of the two groups. Conversions to open repair and technical complications were more frequent with this device and after adjustment the morbidity and mortality rate appeared higher for those treated with AUIC devices, though these findings requires confirmation within a randomised trial.

Larger aneurysms

Larger aneurysms have worse outcomes, with fewer large aneurysms excluded and a higher mortality (Table 7). This is important particularly for unfit patients, who tend to have larger aneurysms. Though often more technically demanding, there was no increase in the rate of technical complications in larger aneurysms, but a trend towards an increase in the need for conversion to open repair.

Assessment of introduction of technique

There was evidence of improving results over time, with a fall in mortality between the first and second year of data submission and a drop in the rate of conversion to open repair. These results can probably be attributed to a number of factors: the effect of the learning curve; better case selection; and improvements in device design.

Length of stay

There are potential early cost savings if the length of hospital stay is reduced and if those treated by endovascular repair do not require intensive care. This must be balanced against the cost of the device and other equipment necessary, and potential cost of treating long-term problems, particularly if the device fails. The difference in postoperative length of stay between patients treated by AT/BI and AUIC devices is probably related to local protocols in the units implanting AUIC devices, and a requirement to recover from the more surgical procedure, the crossover graft in the AUIC group.

Conclusion

The results for short-term outcomes of endovascular AAA repair are encouraging and are similar in terms of morbidity and mortality to conventional surgery. Direct comparison between devices and against conventional surgery should ideally be made within a randomised trial to avoid confounding influences inherent in observational data, such as that collected by registries. Using endovascular repair as an alternative to conventional repair in high-risk unfit patients should be considered carefully in the light of the burden of co-morbid disease and of the likely rate of death and complications in this group, particularly if conversion is required.

Key Messages

- Endovascular repair of AAA is technically feasible, with improved results after the first year.
- The mortality for endovascular repair is similar to reported rates for conventional surgery in fit patients.
- Unfit patients offered treatment in this way had a high death and complication rate.
- A randomised trial with long-term follow-up will be required to compare endovascular repair with

conventional surgery in fit patients and observation in unfit patients.

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